

K954736

This summary is for the:

Trade name	MDT Biologic Company ACCESS (Powerclave)
Common name	sterilizer controls
Classification name	steam sterilizer (per 21 CFR 880.6880)

ref. 21 CFR 807.92(a)(2)

We believe this product to be substantially equivalent to Castle Microcomputer Control K820783.

ref. 21 CFR 807.92(a)(3)

The MDT Biologic Company Access (Powerclave) is an upgrade of an existing microcomputer control system intended to be used with hospital steam sterilizers. Specifically, Access (Powerclave) Steam Sterilizer Controls are to be used with "Castle" brand sterilizers manufactured by MDT Biologic Company for use in industrial, laboratory, and health care facility environments. These sterilizers are intended to be used to sterilize wrapped and unwrapped surgical instruments, and liquids.

The difference between predicate sterilizer controls and the Access controls is that the Access controls are provided with more modern microprocessor/software. and interactive graphic touch screen operator interface. The chamber vessel and piping remain unchanged.

ref. 21 CFR 807.92 (a)(4), (5) & (6)

The ANSI/AAMI ST-8 - 1994 American National Standard for Hospital Steam Sterilizers was used to establish the minimum construction and performance requirements for this product.

This product has also been designed to meet the requirements of UL-544, CSA C22.2, and IEC 601.1 safety standards for medical devices. The vessels are designed and constructed to Section VIII of the ASME pressure vessel code and each vessel is so certified.

We believe the product to conform to the above requirements.

No clinical testing is required for this submittal

ref. 21 CFR 807.92(b)(1), (2) & (3)

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